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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,611	10/08/2004	Annette J Kim	20967YP	4066
210	7590	10/18/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			BALLS, ROBERT J	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 10/18/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/510,611	Applicant(s) KIM ET AL.	
	Examiner R. James Balls	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 13-28 is/are pending in the application.
- 4a) Of the above claim(s) 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-4 and 13-28 are pending.
2. This application is a 371 of PCT/US03/10737 filed on April 8, 2003 which claims benefit of 60/372,644 filed on April 4, 2002.
3. Claims 1-4 and 13 are currently under examination. Applicants cancelled Claims 5-12 and Claims 14-28 are withdrawn as being directed to a non-elected invention.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3 and 13 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject that which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants amended the claims by adding the proviso that -(CR^{1a}₂)n-X-(CR^{1a}₂)p-V-(R²)q is not equivalent to H or CH₃. A search of the specification reveals no antecedent basis for this amendment resulting in the change of scope being new matter. This is a NEW MATTER rejection. Removal of all new matter is required. *In re Rasmussen* 211 USPQ 323 (CCPA 1981). This rejection was necessitated by applicants' amendment to the claims.

Claim Rejections - 35 USC § 102(b)

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of Claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Iddon et al., *Synthesis and Reactions of 2,3,5,6-tetrahydro-2,5-ethano-3-benzazocin-4(1H)-one and a thieno-extended Analog*, J. CHEM. SOC. PERKIN. TRANS., 1(4):1083-1090 (1990) is maintained for the reasons of record. Applicants amended the claims in an attempt to remove the instant reference as prior art resulting in the addition of new matter. After removal of the new matter and restoring the claims to the previous version, the Iddon et al. reference still applies.

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of Claims 1-4 and 14 under 35 U.S.C. §103(a) as being unpatentable over Belanger et al., (U.S. Patent No. 4,332,810) in view of Patani & Lavoie, BIOISOSTERISM: A RATIONAL APPROACH IN DRUG DESIGN, Chem. Rev. 96:3147-3176 (1996) is maintained for the reasons of record.

Applicants contend that the invention as a whole is non-obvious and cite *In re Eli Lilly & Co.* 14 U.S.P.Q. 1741, 1743 (Fed. Cir. 1990) alleging the combined reference

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merely suggest it would be “obvious-to-try” the instant combination without any expectation of success. The argument, however, is not applicable to the instant case, as all the elements of a prima facie case of obviousness are met and obviousness does not require absolute predictability. *In re Kronig and Scharfe*, 190 USPQ 425 (CCPA 1976); *In re PANTZER AND FEIER*, 144 USPQ 415 (CCPA 1965); *Ex parte Erlich* (BdPatApp&Int) 3 USPQ2d 1011 (8/18/1986). In the instant case, Patani & Lavoie teach the proposed modification by providing equivalent functional groups that act as bioisosteres of one another. Bioisosterism is an art-recognized rational design. As applicants point out, Patani & LaVoie show multiple bioisosteric replacements. For example, on page 3150, first column Section 2, the interchange of hydroxyl and amino groups is shown. On page 3155, first column it shows the equivalency of OH, Cl, SH, and Br. Page 3153, Table 12 shows the equivalency of Cl, CH₃, OH, NH₂, and H. Applicants explain that in some cases bromine is less potent than the other listed bioisosteres (p. 3155, Table 16). However, a bioisostere is expected to “elicit similar biological activity” not always *improved* biological activity. See Patani & Lavoie, page 3148, column 1, first full paragraph. Also, the possibility of failure does not render a successful modification unobvious. *In re PANTZER AND FEIER*, 144 USPQ 415 (CCPA 1965). Therefore, a skilled artisan in possession of the structurally similar compounds disclosed in Belanger et al. would be motivated to make the proposed bioisosteric substitutions set forth in Patani & Lavoie with the reasonable expectation of obtaining more compounds exhibiting similar biological activity.

Conclusion

7. No Claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

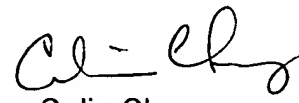
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls
October 6, 2006



Celia Chang
Primary Examiner
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